

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Electronic Pedigree Requirements: Unique Identification Number; Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

Sections Affected: Add Article 5.5 to Title 16 Cal.Code Reg. and Add § 1747 and 1747.1

Specific Purpose of the Proposed Changes:

The Board of Pharmacy ("Board") proposes to add Article 5.5 entitled "Pedigree Requirements" to Title 16 of the California Code of Regulations ("CCR") and to add Sections 1747 and 1747.1 related to requirements for electronic pedigrees of dangerous drugs and devices. The board's proposal would establish the standardized numerical identifier that a drug manufacturer or repackager must establish and apply to the smallest package or immediate container of a dangerous drug or dangerous device. This proposal would also establish dates by which a manufacturer that distributes a dangerous drug or device in California shall submit to the board declarations related to the manufacturer's readiness to comply with statutory electronic pedigree requirements. It would also set forth requirements for manufacturers, wholesalers, repackagers, pharmacies and pharmacy warehouses (as defined in Business and Professions Code section 4163(g)) to submit specified declarations to the board in order to designate dangerous drugs that they possess as "not subject" to the serialized electronic pedigree requirements.

Specifically, the Board's proposed changes would include:

1. The addition of a new Article 5.5 and Title "Pedigree Requirements" in Title 16 in Division 17 of the California Code of Regulations for ease-of-use and reference;
2. The addition of a new definition for "unique identification number" which incorporates by reference the U.S. Food and Drug Administration's guidance document: *"Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages,"* dated March 2010;
3. A requirement for each manufacturer to submit a declaration to the board by December 1, 2014 that includes a list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty percent of the manufacturer's drugs that are ready for initial implementation as of January 1, 2015, as well as a list of dangerous drugs that are not yet ready to be serialized;
4. A requirement for each manufacturer to state in the declaration the methods used to measure the percentage of drugs ready to be serialized, the calculations used to arrive at the percentage, and the technology employed to meet the pedigree requirements;

5. A requirement for each manufacturer to submit a declaration to the board by December 1, 2015 that includes a list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty percent of the manufacturer's drugs that are ready for implementation as of January 1, 2016;
6. A specification that failure to submit or re-submit a declaration compliant with subdivisions (a)(1) or (a)(2) of this Section constitutes a violation of the Pharmacy Law;
7. A requirement for each manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls as "not subject" to pedigree requirements to submit a declaration to the board by August 1, 2016 that includes a list and quantity of dangerous drugs by name and product package (SKU) type acquired prior to July 1, 2016;
8. A requirement for each manufacturer, wholesaler or repackager to state in the declaration the means and source of acquisition and the anticipated means of any subsequent distribution or disposition;
9. A requirement for each pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls as "not subject" to pedigree requirements to submit a declaration to the board by August 1, 2017 that includes a list and quantity of dangerous drugs by name and product package (SKU) type acquired prior to July 1, 2017;
10. A requirement for each pharmacy or pharmacy warehouse to state in the declaration the means and source of acquisition and the anticipated means of any subsequent distribution or disposition; and,
11. A requirement that the board or its designee shall have sole discretion to determine whether declarations submitted pursuant to this Section are compliant and to reject and require re-submission of any non-compliant declaration until determined to be fully compliant.

Factual Basis/Rationale/Problem Addressed

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

In 2004 the California State Board of Pharmacy (the board) sponsored legislation, Senate Bill (SB) 1307, that made comprehensive changes to the drug distribution system to protect against counterfeit drugs. Among other requirements that were enacted, the Pharmacy Law required development of an electronic "pedigree" that tracks each prescription drug ("dangerous drug") at the saleable unit (item) level through the distribution system. Existing law requires each manufacturer of dangerous drugs, and every wholesaler and pharmacy that possesses dangerous drugs to provide specified notices and declarations to the board by specified dates

for compliance with the electronic pedigree laws. (Business and Professions Code sections 4163.2, 4163.5,) However, the form and content of such notices and declarations are not fully specified. In addition, existing law at Business and Professions Code Section 4034 (operative on January 1, 2015) will require each pedigree to include a “unique identification number.” However, the Pharmacy Law does not specify what that unique identification number must contain to be compliant.

Business and Professions Code section 4034 defines a “pedigree” as a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. This statute specifies that a pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all states of distribution, and specifies the information that shall be included in the pedigree, including the requirement of a linked “unique identification number” for each dangerous drug. The statute becomes operative on January 1, 2015.

The board’s proposal at Title 16, CCR Section 1747 would establish requirements for the “unique identification number” that is to be established and applied to the smallest package or immediate container by the manufacturer or repackager by incorporating by reference the U.S. Food and Drug Administration’s guidance from the following document: *“Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages,”* dated March 2010. According to the FDA, the guidance document represents the agency’s current thinking on standards for drug supply chain security-standardized numerical identification for prescription drug packages, and was developed after receiving public comment from stakeholders on this issue.

Business and Professions Code Section 4163 specifies dates on which dangerous drugs shall not be sold, traded, or transferred without providing a pedigree, which includes a unique identification number. Accordingly, adoption of Section 1747 in Title 16 of the California Code of Regulations is necessary to enable the Board to provide advance direction to manufacturers and repackagers to begin the process of meeting Section 4163’s mandates.

Business and Professions Code Section 4163.2 provides for the designation of drugs and the submission of written declarations listing those drugs that are not subject to pedigree requirements, as specified (see also Business and Professions Code section 4163.4), and authorizes the board to establish regulations to specify the requirements and procedures for the creation and submission of these written declarations.

Business and Professions Code Section 4163.5 specifies dates by which each manufacturer of a dangerous drug distributed in California shall designate its readiness with the state’s serialized electronic pedigree requirements by providing the board with information representing specified percentages of drugs that are subject to the state’s serialized electronic pedigree requirements, and specifies that each manufacturer shall designate the measure or measures used in designating its drugs to be serialized, according to the process specified by the board.

The board's proposal at Title 16, CCR Section 1747.1 would establish dates by which declarations shall be submitted to the board, and the required content of those declarations as it relates to the manufacturer's readiness to comply with the state's serialized electronic pedigree requirements. It would also require manufacturers, wholesalers, and repackagers by August 1, 2016 and pharmacies and pharmacy warehouses by August 1, 2017 to submit specified declarations to the board in order to designate dangerous drugs that they possess as "not subject" to the serialized electronic pedigree requirements. The board's proposal would establish that the board or its designee shall have sole discretion to determine whether any of the declarations submitted are compliant, and authorize the board to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant. Further, the board's proposal specifies that failure to submit compliant declarations to the board, as specified, shall constitute a violation of Pharmacy Law. These provisions are necessary to ensure accurate, timely and complete information is being provided to the board prior to making a decision regarding compliance with the electronic pedigree laws. By making non-compliance with these provisions a violation of the Pharmacy Law, this proposal would also provide the board with a mechanism for enforcing compliance with these reporting obligations.

The *"Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages,"* dated March 2010 is referenced in these amendments. It would be cumbersome, unduly expensive and otherwise impractical to publish the documents in the California Code of Regulations. It is available on the board's website and from the board upon request.

Underlying Data

1. Senate Bill 1307, Chapter 713, Filed with the Secretary of State on September 30, 2008
2. "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," dated March 2010, U.S. Food and Drug Administration (FDA).
3. Board of Pharmacy "Questions and Answers Relating to the California Electronic Prescription Drug Pedigree Law(s)," January 2008
4. Letter dated August 25, 2008, by Mark Ridley-Thomas, Senator, 26th District, Chair of the Senate Committee on Business, Professions & Economic Development to Mr. Gregory Schmidt, Secretary of the Senate
5. ***The Script*** (Board of Pharmacy Newsletter), February 2009, "Changes in Pharmacy Law" and "Compliance Dates Extended for e-Pedigree Requirements" (pp. 1-6)
6. Board of Pharmacy Comments re: Enhancing Pharmaceutical Distribution Integrity Act of 2012, Letter Dated June 17, 2012, Signed by Stan Weisser, RPh, President of the Board of Pharmacy, and by Virginia Herold, Executive Officer of the Board of Pharmacy
7. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held May 12, 2012
8. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Enforcement Committee and E-Pedigree Public Meeting held June 12, 2012

9. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held July 17-18, 2012
10. Article "What you need to know now about California e-Pedigree," **Healthcare Packaging**, July 20, 2012 (viewed July 24, 2012)
http://www.healthcarepackaging.com/archives/2012/07/what_you_need_to_know_now_abou.php
11. "California Staggering Its E-Pedigree Regulations," **PMPNews.com**, Published August 7, 2012, on *Pharmaceutical & Medical Packaging News* (<http://www.pmpnews.com>)
12. Economic Impact Analysis

Business Impact

The Board does not believe that this regulation will have a significant adverse economic impact on businesses. Representative businesses have a statutory requirement to have a pedigree that includes a unique identification number which is able to be tracked through an interoperable electronic system (see Business and Professions Code Section 4034). Moreover, the U.S. Food and Drug Administration has provided guidance to industry on standardized numerical identification numbers for prescription drug packages. Thus, the Board believes that its proposal would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The Board's proposal, however, would impose the following reporting, recordkeeping, or other compliance requirements: manufacturers of dangerous drugs would be required to report by way of declaration to the board by December 31, 2014 regarding its initial implementation of the pedigree laws, and thereafter regarding final implementation by December 31, 2015. Additionally, this proposal would also require manufacturers, wholesalers, and repackagers by August 1, 2016 and pharmacies and pharmacy warehouses by August 1, 2017 to submit specified declarations to the board in order to designate dangerous drugs that they possess as "not subject" to the serialized electronic pedigree requirements.

Benefits

Business and Professions Code section 4005 states that "the board may adopt rules and regulations....pertaining to the practice of pharmacy...." Further, Business and Professions Code 4001.1 states that the "protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." The board believes the regulatory changes as described in the Notice will serve to protect the public health by specifying requirements for the initial phase of compliance with California's electronic pedigree requirements. Compliance helps ensure that tracking of drug products occurs consistent with the pedigree laws, resulting in the public being better protected from counterfeited and adulterated dangerous drugs entering California's prescription drug supply chain.

Specific Technologies or Equipment

This regulation would specify the requirements for the “serialized numeric identifier” that would be contained in a pedigree of a dangerous drug, as specified.

Consideration of Alternatives

The Board of Pharmacy has made an initial determination that no reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

The board is authorized by law to implement, interpret or make specific the laws under its jurisdiction (Business and Professions Code sections 4005, 4163.2(a)(3), 4163.5(b),(c)). With respect to the unique identification number, the FDA’s guidance document represents the agency’s current thinking on standards for drug supply chain security-standardized numerical identification for prescription drug packages, and was developed after receiving public comment from stakeholders on this issue. At numerous meetings conducted by the board regarding the development of the unique identification number standard, industry representatives have indicated that the guidance document’s standards were acceptable methods of creating the unique identification number for serialization purposes. No other alternatives were proffered at these meetings; therefore, no others were considered by the board.

The requirements for reporting by way of declaration, including some of the elements contained within the declaration, are set forth in Business and Professions Code section 4163.2 and 4163.5. As this method was designated by the enabling legislation, no other options were considered by the board. The contents of the declarations were discussed at various meetings on the subject and no other options for content were proffered at those meetings. Consequently, no other alternatives were considered.